Remarks/Arguments

Claims 1 to 84, as amended, appear in this application for the Examiner's review and consideration. Claims 1 to 64 and 68 to 84 have been withdrawn by the Examiner in the Office Action dated October 2, 2006 as directed to non-elected subject matter.

The specification has been amended to add the following cross-references to related applications:

> This application claims the benefit of priority to U.S. provisional patent application Serial Nos. 60/432,961, filed December 12, 2002, 60/448,062, filed February 15, 2003, and 60/465,534, filed April 25, 2003, hereby incorporated by reference (emphasis added).

These cross-references are supported by the Patent Application Transmittal Letter submitted on December 12, 2003 (attached hereto as "Attachment A" for the Examiner's convenience), which recites:

> This application claims the benefit of U.S. Provisional Patent Application Serial Numbers Nos. 60/431,961, filed December 12, 2002; 60/448,062, filed February 15, 2003; and 60/465,534, filed April 25, 2003, all of which is incorporated herein by reference (emphasis added).

Applicants respectfully submit that the recitation of U.S. provisional patent application Serial No. 60/431,961, rather than 60/432,961, in the Transmittal Letter was an obvious typographical error on the part of Applicants. The correct serial number of 60/432,961 is supported by the other identifying information provided in the Transmittal Letter, *e.g.*, the filing date of December 12, 2002 and the inventorship. Thus, the correction of this typographical error in the priority claim adds no new matter to the application. Once this amendment to the specification has been entered, Applicants respectfully request that the Office issue a filing receipt that has been updated to include the priority claim to U.S. provisional patent application Serial No. 60/432,961, filed on December 12, 2002. In addition, Applicants are submitting a substitute Declaration reflecting the correct priority claim to U.S. provisional patent application Serial No. 60/432,961.

Claim 65 has been amended to recite "gatifloxacin form CX characterized by at least one of: (i) a powder x-ray diffraction pattern having reflections at about 6.5, 14.6, 17.4, and 19.4°± 0.2° 2θ; and (ii) a differential scanning calorimetry thermogram having endothermic

peaks at about 122°C and about 137°C." This amendment is supported on page 13, lines 4-12 of the application as filed.

Claim 66 has been amended to recite "gatifloxacin form CW characterized by at least one of: (i) a powder x-ray diffraction pattern having reflections at about 5.2, 11.2, 11.5, 14.3, and 22.2° ± 0.2° 2θ; and (ii) a differential scanning calorimetry thermogram having an endothermic peak at about 178°C." This amendment is supported on page 12, lines 18-26 of the application as filed.

Claims 65-67 have also been amended to correct typographical errors and to present the claims in better form. No new matter has been added to the claims.

Claims 65-67 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because the metes and bounds of the claim term gatifloxacin form CX are unclear. Office Action, pp. 3-4. Applicants respectfully traverse.

"Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000) (citing *Personalized Media Comm., LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998)). When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989); M.P.E.P. § 2173.05(a). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Personalized Media Comm.*, 161 F.3d at 705, 48 U.S.P.Q.2d 1180 (citing *Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993).

Claims 65-67, as amended, recite crystalline gatifloxacin form CX "characterized by at least one of: (i) a powder x-ray diffraction pattern having reflections at about 6.5, 14.6, 17.4, and 19.4°± 0.2° 2θ; and (ii) a differential scanning calorimetry thermogram having endothermic peaks at about 122°C and about 137°C." A person of ordinary skill in the art would understand the metes and bounds of the claim term "crystalline gatifloxacin form CX" by reference to the powder x-ray diffraction pattern and/or differential scanning calorimetry thermogram recited in the claims. Accordingly, claims 65-67 meet the legal standard for definiteness and the rejection of the claims under 35 U.S.C. § 112, second paragraph should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

Dated: April 2, 2007

By: Gina R. Gencarelli

Gina R. Gencarelli
Reg. No. 59,729

KENYON & KENYON LLP
One Broadway
New York, NY 10004
Direct Dial: 212-908-6434
Facsimile: 212-425-5288

ATTACHMENT A